

M E M O R A N D U M**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS**

DATE: September 8, 1999
FROM: Robert L. West *Robert L. West*
Director, Division of Labeling and Program Support
SUBJECT: Statistical Report - August 1999
TO: See Below

This memorandum provides a copy of the Office of Generic Drugs' statistical report for August 1999.

Tables I through III detail quantitative information about OGD's receipts, actions, and pending review status for both original and supplemental (CMC and labeling) applications for the past month and for the 11 preceding months. Table IV pertains only to original (unapproved) applications and is entitled "Old Counting System". This table is helpful in comparing quantitative data between OGD's current and former counting systems. Following the tables, graphic presentations of selective quantitative data are provided. These graphs allow comparisons to similar data dating back to 1991. Where appropriate, the graphs have been modified to reflect the change of AADAs to ANDAs as a result of the elimination of Section 507 of the FD&C Act under FDAMA.

Lists of August's 13 approved, and 7 tentatively approved drug products follow the graphic presentations. The approved list reveals that two applicants also received approval of supplemental applications providing for additional strengths of a previously approved drug product. In addition, OGD issued a second tentative approval letter to two applicants who were unable to be approved due to patent challenge issues.

First time generic approvals or tentative approvals are indicated by an asterisk (*).

The following observations are notable for the August data:

The total number of major, minor, and facsimile amendments to unapproved applications received during the month (173) exceeded monthly totals for the past 12 months.

The number of overdue original applications (pending > 180 days) is at its lowest level (76) since January 1999.

908-0308

M645

It has been since October 1998 since our Labeling Review Branch approved a greater number of supplemental applications (54). The last time a greater number of incoming amendments to labeling supplements was received by the branch was December 1998.

cc:

Office of Pharmaceutical Science

HFD-003/R.Williams

HFD-003/H.Winkel

Office of Generic Drugs

HFD-600/D.Sporn

HFD-601/G.Buehler

~~HFD-600/M.Lamb~~/Forward to Documents Management Branch,

Docket # 90S0308

HFD-600/M.Fanning

HFD-600/R.Hassall

HFD-600/R.Warzala

HFD-604/D.Hare

HFD-610/R.West

HFD-610/DLPS File

HFD-611/P.Rickman

HFD-613/J.Grace

HFD-613/C.Hoppes

HFD-615/H.Greenberg

HFD-617/P.Beers-Block

HFD-620/R.Patel

HFD-621/A.Rudman

HFD-623/D.Gill

HFD-625/M.Smela

HFD-629/P.Schwartz

HFD-630/A.Mueller

HFD-640/F.Holcombe

HFD-640/F.Fang

HFD-641/V.Sayeed

HFD-643/R.Adams

HFD-645/B.Arnwine

HFD-647/U.Venkataram

HFD-649/G.Smith

HFD-650/D.Conner

HFD-651/R.Patnaik

HFD-652/Y.C.Huang

HFD-655/S.Nerurkar

HFD-658/B.Davit

HFP-020/W.Hagan

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Center for Drug Evaluation and Research - Office of Generic Drugs
Quantitative Report

Table I .

ORIGINAL APPLICATIONS

	Sep-98	Oct-98	Nov-98	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	26	24	39	47	27	25	22	19	20	25	33	20	327	27	26	28
AMENDMENTS	116	129	109	130	107	123	163	125	122	101	138	173	1536	128	137	103
- MAJOR	62	61	44	62	40	76	74	55	52	44	61	86	717	60	64	53
- MINOR	24	24	29	32	27	18	45	25	34	26	42	44	370	31	37	27
- FACSIMILE **	30	44	36	36	40	29	44	45	36	31	35	43	449	37	36	22
-- ACTIONS --																
APPROVALS	26	13	17	28	10	14	15	21	18	19	17	13	211	18	16	18
TENTATIVE APPROVALS+	2	10	9	6	6	5	5	2	4	6	4	7	66	6	6	2
NOT APPROVABLE	32	34	50	29	16	27	55	34	37	54	62	36	466	39	51	37
FACSIMILE REQUEST**	22	26	15	20	9	20	20	19	17	20	29	12	229	19	20	17
REFUSE TO FILE	9	5	5	10	6	11	3	5	5	2	7	12	80	7	7	4
WITHDRAWALS	24	97	4	37	16	2	10	50	28	21	50	36	375	31	36	34
- OF APPROVED	17	93	2	16	14	0	2	44	16	21	46	25	296	25	31	28
- OF UNAPPROVED	7	4	2	21	2	2	8	6	12	0	4	11	79	7	5	6
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	417	405	407	422	438	442	439	437	436	409	399	409		422	406	397
AWAITING OGD ACTION (> 180 DAYS)***	97	99	88	88	79	105	98	99	98	100	84	76		93	87	76
AWAITING OGD ACTION (≤180 DAYS)***	320	306	319	334	359	337	341	338	338	309	315	333		329	319	320

* Please see last page of this report for numbers represented by the old counting system as reported in prior months.

** Facsimile policy went into effect in January of 1997

*** In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being by fraud. Review status figures reported since this date exclude suspended applications. As of August 31, 1999, 1 original application and 16 supplements were Upon completion of validity assessments, suspended applications may be returned to active pending status.

+ Note: Tentative approvals are counted as approvals subsequently when approved. For example 25 of the 211 approvals for the year ending August 31, 1999 were previously reported as tentatively approved applications. The 2 tentative approvals reported in April 1999 are actually approvable actions. One of the tentative approvals reported in May 1999 is actually an approvable action.

Center for Drug Evaluation and Research - Office of Generic Drugs
Quantitative Report

Table II

POST APPROVAL SUBMISSIONS TO APPLICATIONS (CHEMISTRY)

	Sep-98	Oct-98	Nov-98	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	366	197	211	389	188	150	148	157	193	260	215	291	2765	230	255	229
AMENDMENTS TO SUPPLEMENTS **	134	205	286	156	125	158	404	185	249	239	145	335	2621	218	240	224
--SUPPLEMENTAL ACTIONS--																
APPROVALS ***	152	187	174	446	39	310	283	134	235	177	143	98	2378	198	139	172
APPROVABLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE +	102	50	68	77	21	77	328	94	76	180	83	103	1259	105	122	71
WITHDRAWALS	8	11	8	84	1	11	23	16	5	25	21	28	241	20	25	25
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL) *	1862	1925	1905	1749	1866	1737	1362	1355	1298	1260	1234	1398		1579	1297	1356
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	141	251	213	234	243	237	128	137	139	156	85	83		171	108	106
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1721	1674	1692	1515	1623	1500	1234	1218	1159	1104	1149	1315		1409	1189	1251

* In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by
by fraud. Review status figures reported since this date exclude suspended applications. As of August 31,
Upon completion of validity assessments, suspended applications may be returned to active pending status.

** March 1999 figure includes 203 amendments to supplements submitted by one applicant.

*** March 1999 figure includes approval of "global" supplements submitted by single applicant.

+ March 1999 figure includes a total of 290 not approvable actions taken on "global" supplements submitted by 2 individual applicants.

Center for Drug Evaluation and Research - Office of Generic Drugs

Table III

Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Sep-98	Oct-98	Nov-98	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-RECEIPTS-																
ORIGINAL SUPPLEMENTS	34	94	46	59	41	33	61	41	40	38	42	31	560	47	37	56
AMENDMENTS TO SUPPLEMENTS	45	67	40	78	55	49	55	38	60	44	50	60	641	53	51	56
-SUPPLEMENTAL ACTIONS-																
APPROVALS	61	60	46	39	39	31	40	46	54	47	49	54	566	47	50	52
APPROVABLE	7	4	6	13	4	17	3	4	2	5	4	12	81	7	7	8
NOT APPROVABLE	15	8	7	17	5	5	23	32	14	14	24	17	181	15	18	12
WITHDRAWALS	4	1	3	0	0	4	25	1	3	7	0	4	52	4	4	4
-REVIEW STATUS-																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	287	303	314	318	338	339	349	323	308	299	282	256		310	279	371
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	112	109	120	125	137	116	109	114	106	117	117	95		115	110	149
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	175	194	194	193	201	223	240	209	202	182	165	161		195	169	221

* In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by fraud. Review status figures reported since this date exclude suspended applications. As of August 31, Upon completion of validity assessments, suspended applications may be returned to active pending status.

Center for Drug Evaluation and Research - Office of Generic Drugs

Table IV.

Quantitative Report

ORIGINAL APPLICATIONS - OLD COUNTING SYSTEM

	Sep-98	Oct-98	Nov-98	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	45	46	66	73	41	44	34	28	33	38	50	29	527	44	39	45
AMENDMENTS	116	129	109	130	107	123	163	125	122	101	138	173	1536	128	137	103
- MAJOR	62	61	44	62	40	76	74	55	52	44	61	86	717	60	64	53
- MINOR	24	24	29	32	27	18	45	25	34	26	42	44	370	31	37	27
- FACSIMILE	30	44	36	36	40	29	44	45	36	31	35	43	449	37	36	22
-- ACTIONS --																
APPROVALS	45	21	27	47	13	16	18	33	23	21	31	20	315	26	24	29
TENTATIVE APPROVALS+	5	17	15	8	8	11	13	2	9	15	10	14	127	11	13	3
NOT APPROVABLE	44	47	94	49	29	47	91	57	54	93	100	51	756	63	81	56
FACSIMILE REQUEST*	22	26	15	20	9	20	20	19	17	20	29	12	229	19	20	17
REFUSE TO FILE	14	10	8	13	6	12	4	6	6	5	8	15	107	9	9	6
WITHDRAWALS	27	97	4	41	18	5	11	52	30	21	50	39	395	33	37	36
- OF APPROVED	20	93	2	17	14	0	2	45	16	21	46	25	301	25	31	28
- OF UNAPPROVED	7	4	2	24	4	5	9	7	14	0	4	14	94	8	6	8
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)**	655	647	647	677	709	719	714	705	727	680	663	698		687	680	597
AWAITING OGD ACTION (> 180 DAYS)	142	147	122	138	118	153	154	157	168	177	146	135		146	153	113
AWAITING OGD ACTION (≤180 DAYS)	513	500	525	539	591	566	560	548	559	503	517	563		540	528	484

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Quantitative Report

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Center for Drug Evaluation and Research - Office of Generic Drugs

Table III

Quantitative Report

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Center for Drug Evaluation and Research - Office of Generic Drugs
Quantitative Report

Table IV

ORIGINAL APPLICATIONS - OLD COUNTING SYSTEM

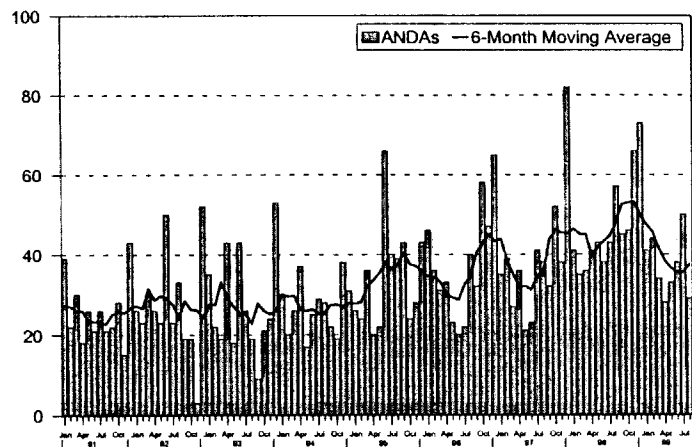
	Sep-98	Oct-98	Nov-98	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
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REFUSE TO FILE	14	10	8	13	6	12	4	6	6	5	8	15	107	9	9	6
WITHDRAWALS	27	97	4	41	18	5	11	52	30	21	50	39	395	33	37	36
- OF APPROVED	20	93	2	17	14	0	2	45	16	21	46	25	301	25	31	28
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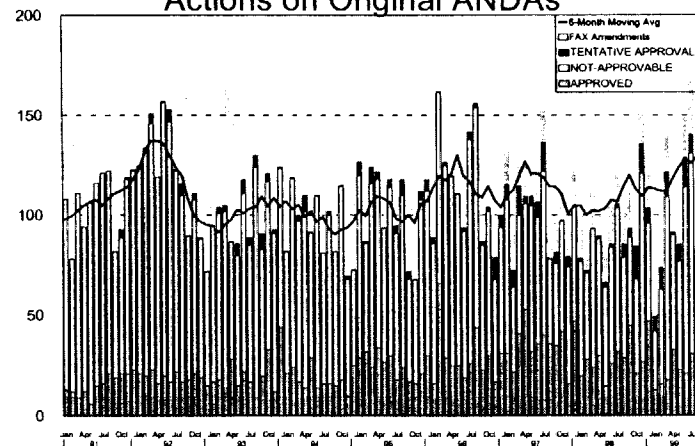
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Original ANDAs Received

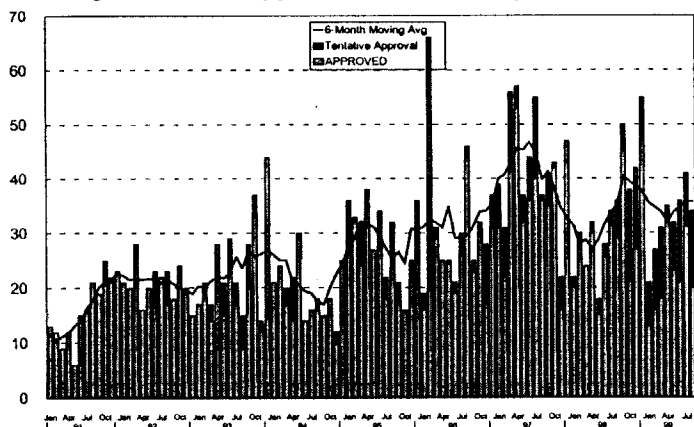


Actions on Original ANDAs



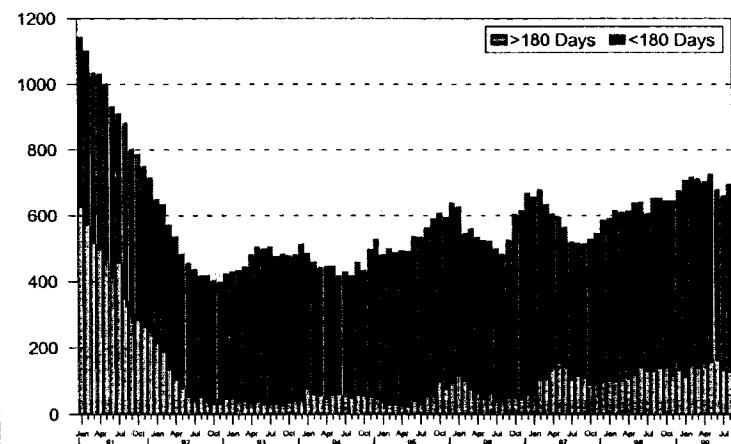
NOTE: TENTATIVE APPROVALS ARE APPLICATIONS THAT HAVE BEEN APPROVED BY THE OFFICE PENDING PATENT EXPIRATION. TENTATIVE APPROVALS ARE COUNTED AS APPROVALS SUBSEQUENTLY WHEN APPROVED.

Original ANDAs Approved or Tentatively Approved

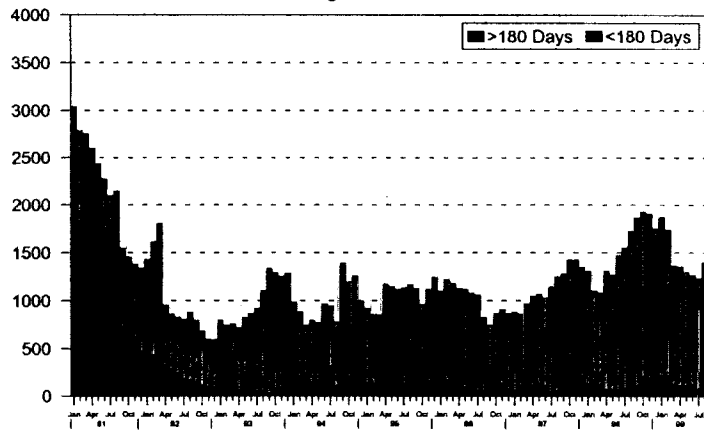


NOTE: TENTATIVE APPROVALS ARE APPLICATIONS THAT HAVE BEEN APPROVED BY THE OFFICE PENDING PATENT EXPIRATION. TENTATIVE APPROVALS ARE COUNTED AS APPROVALS SUBSEQUENTLY WHEN APPROVED. FOR EXAMPLE 44 OF 58 APPROVALS FOR FEBRUARY 1996 WERE PREVIOUSLY TENTATIVELY APPROVED. THE LARGE NUMBER OF APPROVALS RESULTED FROM A DRUG COMING OFF PATENT IN FEBRUARY.

Original ANDAs Pending Per Month

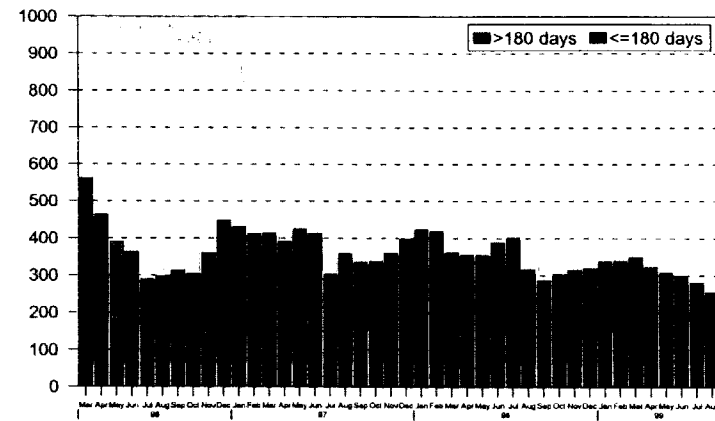


Chemistry, Manufacturing & Controls Supplements Awaiting OGD Action

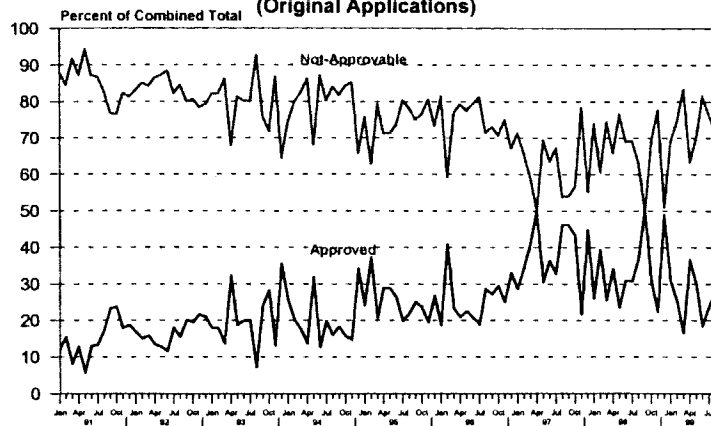


Please note that abrupt changes in the level of pending supplements (e.g. the increase in September 1994) are the result of global submissions to all applications held by a single firm. Changes other than these will be evaluated separately.

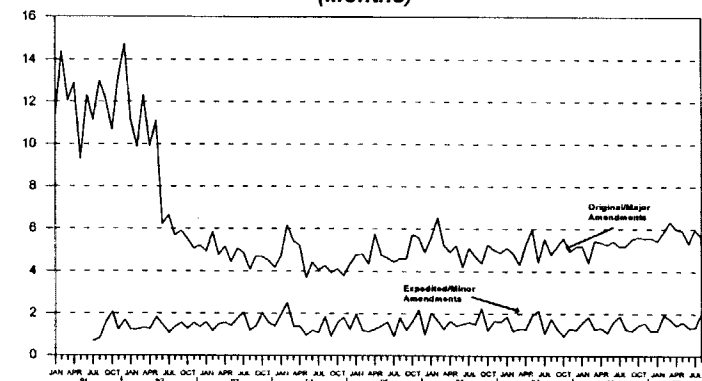
Labeling Supplements Awaiting OGD Action



Percent Approved and Not-Approvable Per Month (Original Applications)



Median ANDA CMC Supplement Review Time (Months)

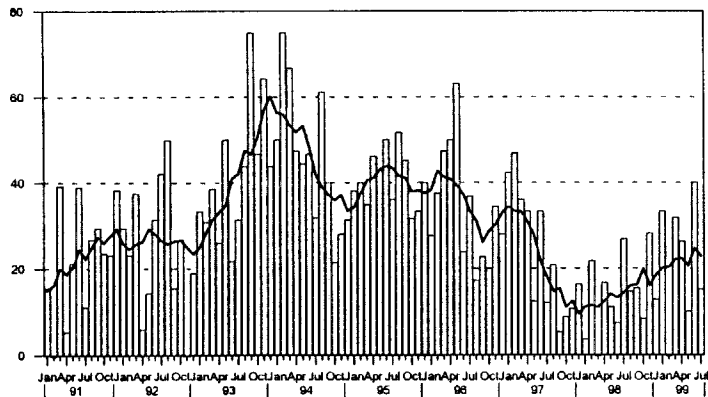


1: Times correspond to actual applications received. The new ANDA/ANDA submission policy that went into effect (1/91) allows certain submissions in a drug product to be included in a single application.

2: In September, 1991 the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being termed by fraud. All initial two level submissions from review time above for the period after 9/91. However, before the AIP went into effect, the review of many applications suspected of containing fraudulent data were suspended. These suspensions were not recorded in the MTS and are not reflected in the above chart.

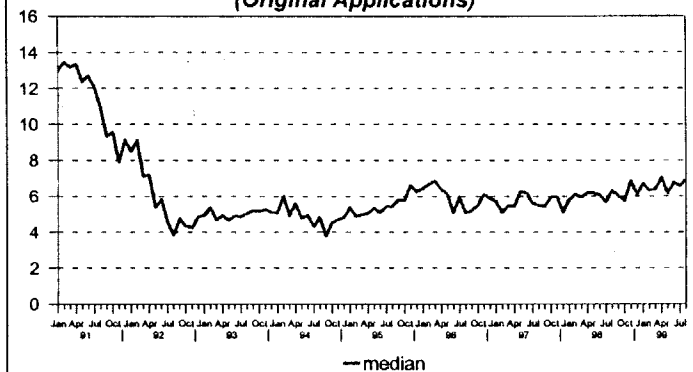
Note: Global Supplements Collapsed

**Percent of Original Submissions with Refuse to File Action
By Month of Receipt**



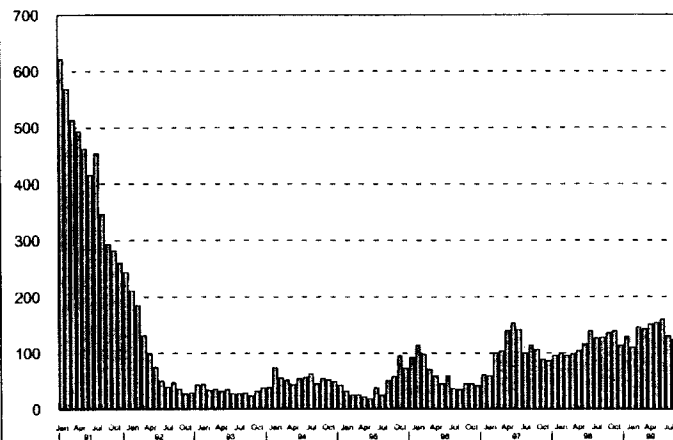
Status as of September 3, 1999. Percentages for recent months may increase due to future RF actions (Actual applications, new counting system)

**Median ANDA Review Cycle (Months)
(Original Applications)**



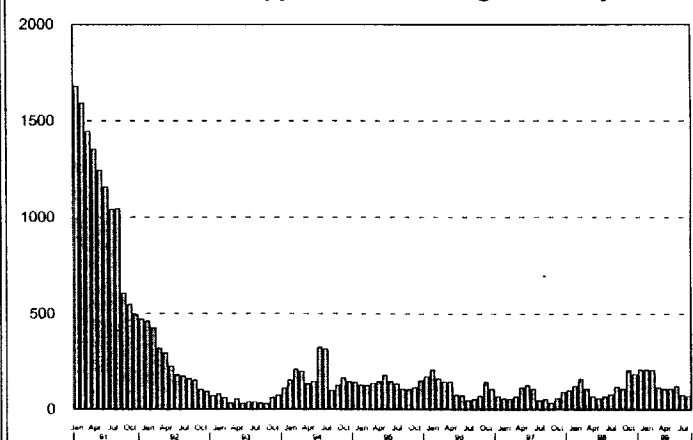
1: These correspond to actual applications received. The new ANDA/ANDA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.
2: In September, 1991 the OGD asserted implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. All time has been subtracted from review time above for the period after 9/91. However, before the AIP went into effect, the review of many applications suspected of containing fraudulent data were suspended. These suspensions were not recorded in the MIS and are not reflected in the above chart.

Original ANDAs Pending > 180 Days



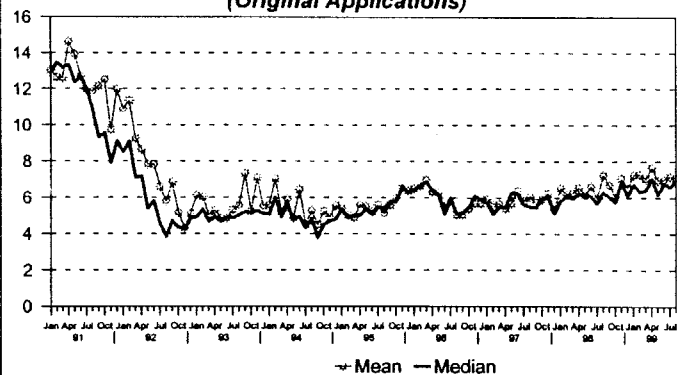
Source: OGD Monthly Report

ANDA CMC Supplements Pending > 180 Days



Source: OGD Monthly Report

Mean and Median ANDA Review Cycle (Months) **(Original Applications)**



1: Times correspond to actual applications received. The new ANDA/ANDA submission policy that went into effect 1-1-91 allows certain variations in a drug product to be included in a single application.

2: In September, 1991 the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP here has been subtracted from review time above for the period after 9/91. However, before the AIP went into effect, the review of many applications suspected of containing fraudulent data were suspended. These suspensions were not recorded in the MIG and are not reflected in the above chart.

By: [illegible]

Office Of Generic Drugs ANDAs Approvals

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Wednesday, September 08, 1999

1. 75-093	PENTOXIFYLLINE EXTENDED-RELEASE TABLETS 400 MG	IMPAX PHARMACEUTICALS, INC.	8/10/99
2. 89-424 S-018	SPIRONOLACTONE TABLETS, USP 50 MG 100 MG	MUTUAL PHARMACEUTICAL COMPANY, INC.	8/11/99
3. 75-256	DESOGESTREL AND ETHINYL ESTRADIOL TABLETS 0.15 MG/0.03 MG (21-DAY CYCLE) 0.15 MG AND 0.03 MG (28-DAY CYCLE)	DURAMED PHARMACEUTICALS, INC.	8/12/99
4. 40-032	CYCLOPHOSPHAMIDE TABLETS, USP 25 MG 50 MG	ROXANE LABORATORIES, INC.	8/17/99
5. 74-792 S-001	GLYBURIDE TABLETS USP (MICRONIZED) 6 MG	MYLAN PHARMACEUTICALS, INC.	8/17/99
6. 40-336	BUTALBITAL, ACETAMINOPHEN, AND CAFFEINE TABLETS, USP 50 MG/500 MG/40 MG	WEST-WARD PHARMACEUTICAL CORP.	8/18/99
7. 75-149	TICLOPIDINE HYDROCHLORIDE TABLETS 250 MG	TEVA PHARMACEUTICALS, USA	8/20/99
8. 75-253	TICLOPIDINE HYDROCHLORIDE TABLETS 250 MG	PUREPAC PHARMACEUTICAL CO.	8/20/99
9. 75-318	TICLOPIDINE HYDROCHLORIDE TABLETS 250 MG	INVAMED, INC.	8/20/99
10. 75-326	TICLOPIDINE HYDROCHLORIDE TABLETS 250 MG	EON LABS MANUFACTURING, INC.	8/20/99
11. 75-218	VECURONIUM BROMIDE FOR INJECTION 10 MG/10 ML & 20 MG/20 ML	ESI LEDERLE	8/23/99

12. 74-688	VECURONIUM BROMIDE FOR INJECTION 10 MG/10 ML & 20 MG/20 ML.	GENSIA SICOR PHARMACEUTICALS, INC.	8/25/99
13. 40-359	ESTROPIRATE TABLETS, USP 0.75 MG 1.5 MG 3 MG	MYLAN PHARMACEUTICALS, INC.	8/26/99
14. 75-371	DACARBAZINE FOR INJECTION, USP 100 MG/VIAL & 200 MG/VIAL	AMERICAN PHARMACEUTICAL PARTNERS, INC.	8/27/99
15. 75-528	CLOMIPHENE CITRATE TABLETS, USP 50 MG	PAR PHARMACEUTICAL, INC.	8/30/99

Office of Generic Drugs ANDAs Tentative Approvals

Page: 1

08-Sep-99

1.	75-476	CARTEOLOL HYDROCHLORIDE OPHTHALMIC SOLUTION, USP 1%	ALCON LABORATORIES, INC.	8/20/99
2.	75-461	NIZATIDINE CAPSULES, USP 150 MG 300 MG	ZENITH GOLDLINE PHARMACEUTICALS, INC.	8/26/99
3.	75-302	FAMOTIDINE TABLETS, USP 20 MG 40 MG	GENEVA PHARMACEUTICALS, INC.	8/30/99
4.	75-490	DOXAZOSIN MESYLATE TABLETS 1 MG (BASE) 2 MG (BASE) 4 MG (BASE) 8 MG (BASE)	ESI LEDERLE, INC.	8/30/99
5.	75-243	MIDAZOLAM HYDROCHLORIDE INJECTION 1 MG (BASE)/ML 5 MG (BASE)/ML	ESI LEDERLE, INC.	8/31/99
6.	75-324	MIDAZOLAM HYDROCHLORIDE INJECTION 1 MG (BASE)/ML 5 MG (BASE)/ML	BAXTER PHARMACEUTICAL PRODUCTS, INC.	8/31/99
7.	75-405	CLADRIBINE INJECTION 1 MG/ML (10 ML VIAL)	BEDFORD LABORATORIES	8/31/99